

REMARKS

1. Disposition of Claims

Claims 1-2, 4-5, 7-8, 10-11, 13-14, 16-17, 19-20, 22-23 and 25-51 are pending in this application. Of these, Claims 1-2, 4-5, 7-8, 10-11, 13-14, 16-17, 19-20, and 22-23 were examined. Claims 1-2 and 13-14 have been amended, for which support is found in the original claims and the specification at paragraph [0008]. No new matter has been added. Reexamination and reconsideration of the application, as amended, are respectfully requested.

2. Compliance with 35 USC 112/2 definiteness

The issue is whether Claims 2, 5, 8, 11, 14, 17, 20, and 23 are in compliance with 35 USC 112/2 as being indefinite for recitation of the expression "memory scores". The rule according to MPEP 2173.02 is that definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

The content of the particular application disclosure: The claims are directed to methods for predicting the likelihood that a human will have impaired or enhanced hippocampal dependent verbal memory, assayed with memory scores. Specification at paragraph [0008]: "Schizophrenia, a complex genetic disorder, appears to involve hippocampal (HIP) abnormalities, including deficits in verbal memory ... Verbal memory deficits ... are also found in unaffected sibs of patients, suggesting a genetic trait related to susceptibility. We hypothesized that the met66val polymorphism would affect verbal memory ... We assessed verbal memory in 184 patients with schizophrenia, 283 siblings, and 101 controls. ... The effect of genotype was significant across all groups for memory scores (p<0.008). The rarer met allele was associated with poorer performance. BDNF genotype had no effect on IQ or prefrontal cognitive measures." [Emphases added.]

The teachings of the prior art: Neuropsychological tests were known in the art, e.g., Egan et al., Biol. Psychiatry 50: 98 (Nov 2001), of record, and Weickert et al., Arch. Gen. Psychiatry 57: 907 (2000), of record.

The claim interpretation: The Wechsler Memory Scale-revised version (WMS-R) and the California Verbal List Test (CVLT) were known to be used to assess verbal (also known as declarative) memory, and different tests were known to be used to assess other types of memory, for example, letter and category fluency for semantic memory and the Wisconsin Card Sorting Test (WCST) for working memory/executive function. Egan et al. 2001 at paragraph bridging p. 99-100; and Weickert et al. 2000 at p. 908, paragraph titled "Neuropsychological Tests".

Putting it all together, the expression "memory scores" would have been understood by one possessing the ordinary level of skill in the pertinent art at the time the invention was made as meaning a measurement of a memory test, here, verbal memory, particularly hippocampal dependent verbal memory ("appears to involve hippocampal (HIP) abnormalities, including deficits in verbal memory").

The CVLT was considered to have a larger "prefrontal component", according to Kopelman et al., Brain 121: 875 (1998), of record, compared to the WMS-R, thus excluding it as a test of verbal memory that is hippocampal dependent, and leaving the WMS-R as a valid test of hippocampal dependent verbal memory.

In sum, the expression "memory scores" would have been understood as meaning a measurement of hippocampal dependent verbal memory, for example, by using the WMS-R test and other such tests of hippocampal dependent verbal memory. When analyzed, not in a vacuum, but in light of the above factors, the conclusion is that Claims 2, 5, 8, 11, 14, 17, 20, and 23 are in compliance with 35 USC 112/2.

3. Compliance with 35 USC 112/1 written description

The issue is whether the content of the amendment to the claims, namely, impaired or enhanced hippocampal function or verbal memory, is new matter. Under MPEP 2163.07, amendments to the application which are supported in the original description are not new matter. There is exact antecedent basis for the recitation impaired or enhanced hippocampal function or verbal memory at original claims 1, 2, 13, and 14.

Another issue is whether the content of the amendment to the claims, namely, hippocampal dependent verbal memory, is new matter. To reiterate, under MPEP 2163.07, amendments to the application which are supported in the original description are not new matter. There is exact antecedent basis for the recitation hippocampal dependent verbal memory

at paragraph [0008] (“appears to involve hippocampal (HIP) abnormalities, including deficits in verbal memory”).

As both amendments to the application are supported in the original description, the conclusion is that the content of the amendments to the claims are not new matter.

The last issue is how the claims were amended to conform to issued US Patent No. 6,458,541 to Sklar et al. The rejection under 35 USC 102(e) vis-à-vis Sklar et al. has been determined to be moot in view of the amendment to the claims. US Patent 6,458,541 to Sklar et al. describes the val allele as deleterious and indicative of bipolar disorder in individuals. In the present application, the claims require that the met allele is deleterious and indicative of not schizophrenia but impaired hippocampal function and hippocampus dependent verbal memory in humans. The claims conform to issued US Patent No. 6,458,541 to Sklar et al. in the sense that both are methods for predicting the likelihood of (for Sklar et al.) the val allele being deleterious and indicative of bipolar disorder and (for the applicant) the met allele being deleterious and indicative of not schizophrenia but impaired hippocampal function and hippocampus dependent verbal memory.

4. Compliance with 35 USC 112/1 enablement

The United States Patent and Trademark Office (USPTO) rejected the claims under 35 USC 112/1 as failing to meet the enablement requirement. Under MPEP 2164, the test for enablement is whether one skilled in the art could make or use the subject matter defined by the claims without undue experimentation. Under MPEP 2164.01(a), the “Wands” factors (the nature of the invention and breadth of the claims, the amount of direction/guidance and presence/absence of working examples, the state of the prior art and the predictability or unpredictability of the art, the level of skill in the art, and the quantity of experimentation needed to make or use the invention) are to be considered in determining whether any necessary experimentation is undue. Here, the specification is enabling with respect to the claimed subject matter for the reasons giving in Declaration under 37 CFR 1.132 of Daniel R. Weinberger, M.D. Thus, here, considering all the factors related to the enablement issue, it must be concluded that the specification is enabling with respect to the claims at issue.

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CONCLUSION

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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AMEND

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